## Required Supplementary Stewardship Information

## **Investment in Research and Development**

For the Fiscal Year Ended September 30, 2001

The many research and development programs in HHS include the following:

DA has two programs that meet the requirements of research and development investments: Orphan Products Development (OPD) Program and FDA Research Grants Program. While FDA's center components conduct scientific studies, FDA does not consider this type of research as "research and development" because it is used to support FDA's regulatory policy and decision-making processes.

The OPD Program was established by the Orphan Drug Act (PL 97-414, as amended) with the purpose of identifying orphan products and facilitating their development. An orphan product is a drug, biological product, medical device, or medical food that is intended to treat a rare disease or condition (i.e., one with a prevalence of fewer than 200,000 people in the United States.)

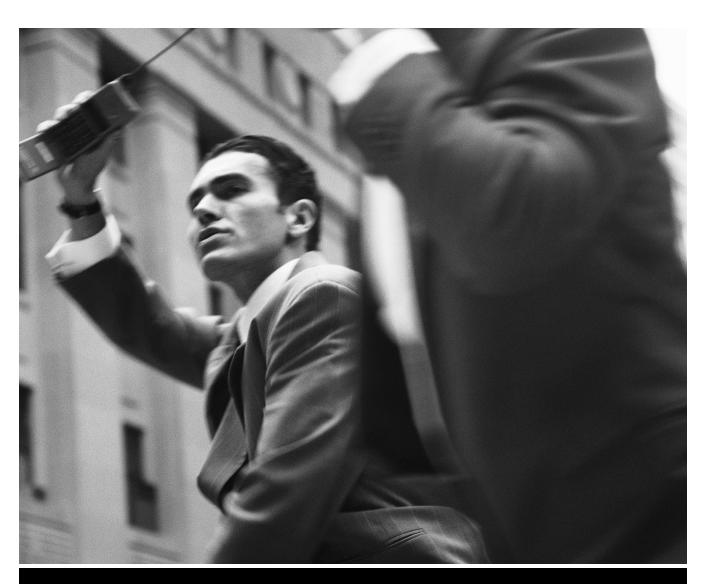
he FDA Research Grants Program is a grants program which is listed as No. 93-103 under the Catalog of Federal Domestic Assistance, whose purpose is to assist public and nonpublic institutions and for-profit organizations to establish, expand, and improve research, demonstration, education, and information dissemination activities concerned with a wide variety of FDA areas.

HIV/AIDS prevention, Infectious Diseases, and Environmental and Occupational Health were the primary areas where CDC's research and development was invested.

¶he NIH Research Program includes all aspects of the medical research continuum. including basic and disease-oriented research, observational and population-based research, behavioral research, and clinical research, including research to understand both health and disease states, to move laborafindings torv into medical applications, to assess new treatments or compare different treatment approaches; and health services research. Furthermore, NIH regards the expeditious transfer of the results of its medical research for further development and commercialization of products of immediate benefit to improved health as an important mandate.

HRSA and AHRQ oversee research and development programs intended to increase or maintain national economic productivity capacity.





## **Investment in Research and Development**

| OPDIV  | Basic   | Applied | Develop-<br>mental | 2001     | 2000     | 1999     | 1998     | 1997  | Total    |
|--------|---------|---------|--------------------|----------|----------|----------|----------|-------|----------|
| ACF    |         | \$31    |                    | \$31     | \$30     | \$19     | \$13     | N/A   | \$93     |
| AHRQ   |         | 127     |                    | 127      | _        | 97       | 139      | N/A   | 363      |
| CDC    |         | 557     |                    | 557      | 505      | 433      | 398      | \$323 | 2,216    |
| FDA    |         | 23      | \$3                | 26       | 26       | 18       | 53       | N/A   | 123      |
| HRSA   | \$16    |         |                    | 16       | 15       | 18       | 44       | N/A   | 93       |
| NIH    | 9,593   | 6,395   |                    | 15,988   | 14,690   | 13,580   | 11,038   | N/A   | 55,296   |
| Totals | \$9,609 | \$7,133 | \$3                | \$16,745 | \$15,266 | \$14,165 | \$11,685 | \$323 | \$58,184 |